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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

PORTLAND DIVISION

UNITED STATES OF AMERICA,	**CIVIL NO.:**
Plaintiff,	
v.	**COMPLAINT FOR PERMANENT INJUNCTION**
JAMES G. COLE and JULIE D. GRAVES, individuals, and **JAMES G. COLE, INC.,** a corporation,	
Defendants.	

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain James G. Cole and Julie D. Graves, individuals, and James G. Cole, Inc., a corporation, from violating:

a. 21 U.S.C. § 331(d), by introducing or delivering, and/or causing to be introduced or delivered, into interstate commerce any new drug within the meaning of 21 U.S.C. § 321(p) that is neither approved under 21 U.S.C. § 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

b. 21 U.S.C. § 331(a), by introducing or delivering, and/or causing to be introduced or delivered, into interstate commerce any article of drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1);

c. 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use;

d. 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

e. 21 U.S.C. § 331(k), by causing articles of food (dietary supplements) that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

JURISDICTION AND VENUE

2. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper under 28 U.S.C. § 1391(b) & (c).

DEFENDANTS

4. Defendant James G. Cole, Inc. ("the firm") is a privately-held Oregon corporation that was founded in 2003. The firm has four full-time employees, and operates from its headquarters located at 1020 Wasco Street, Hood River, Oregon. The firm manufacturers and distributes its products under several names, including "Maxam Labs", "Advanced Sports Nutrition", and "Maxam Nutraceutics."

5. Defendant James G. Cole is the firm's President, Secretary, and sole board member.

6. Defendant Julie D. Graves is the firm's General Manager and controls the day-to-day operations of the firm's facilities.

7. Defendants promote and distribute more than forty-seven (47) products, including PCA, PCA-Rx, C-60, ACAI Resvertrol, Cytomune, Anavone, Liver Rescue, and Probiotics Rx.

8. Defendants receive raw material powder from their sole supplier located in Rockport, Massachusetts. Defendants then process the raw material powder into finished product, pack, and distribute the product from their Oregon facility.

9. Defendants operate several websites, including www.maxamlabs.com and ssl.a-s-n.com. Defendants are solely responsible for the content of these websites.

10. Defendants sell their products in interstate commerce directly to consumers and to other distributers through their website and telephone orders.

CERTAIN OF DEFENDANTS' PRODUCTS ARE DRUGS UNDER THE ACT

11. Under the Act, a product is a drug if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1)(B).

12. The intended use of a product may be determined from any relevant source, including labeling. 21 C.F.R. § 201.128.

13. The Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The Supreme Court has held that the term "accompanying" in the second clause of 21 U.S.C. § 321(m) is not restricted to labels that are on or in the article at issue and that physical attachment to the article is not necessary. See Kordel v. United States, 335 U.S. 345, 349-50 (1948).

14. Defendants promote certain of their products for use as drugs, as evidenced by statements made on their websites, www.maxamlabs.com and ssl.a-s-n.com, as well as sites linking to Defendants' Facebook page. These websites are part of an integrated distribution scheme for Defendants' products because they contain Defendants' phone number and address

from which customers can purchase Defendants' products, as well as the means to order Defendants' products directly through these sites. Defendants also promote their products through brochures, which are available upon request, and on the products' labels.

15. Defendants' websites, product brochures, and labels make drug claims about certain of their products demonstrating that the products are to be used in the diagnosis, cure, mitigation, treatment, or prevention of numerous diseases, including autism, Alzheimer's, cancer, fibromyalgia, ADHD, rheumatoid arthritis, and heart disease, among other conditions. For example, Defendants make the following claims for their products:

a. ***PCA-Rx**, Maxam Nutraceutics' most recognized product, is a proven, natural chelation alternative … recovery for environmentally induced cases of Alzhiemer's, Autism, Fibromyalgia…*

b. *Benefits: Removes cardio and cerebral vascular plaque … Helps rid the body of harmful mycoplasmas … infection with pathogens including mycoplasma are of great concern to those suffering from environmental illnesses including chronic fatigue syndrome (ME/CFS), fibromyalgia, ... autism, ... **PCA** is designed to aid sufferers of environmental illness (EI) ...*

c. *The effects of antioxidant supplementation* [**PCA, C-60, and ACAI Resveratrol**]*... prevent the development of many diseases, such as cancer, heart disease, rheumatoid arthritis, and high cholesterol.*

d. *"I had been undiagnosed (and untreated) for an acute neurological condition with a co-infection for 8 months before landing in the hospital. I have been through many treatments: IV antibiotics…oral antibiotics… I began taking **PCA**, **Cytomune** and **Anavone** and my conditions were significantly reduced and alleviated within a week..."*

e. *Enterococcus faecalis TH 10* [contained in **Probiotics**] … *eliminate the toxins produced by unhealthy bacteria.*

f. [**Liver Rescue**] *Contains: Milk Thistle...Milk thistle extract is so powerful it has been reported to counteract even overdose of otherwise lethal drugs! ... It has been shown, among other things, to nutritionally support persons with skin cancer.*

16. As evidenced by these claims, and many others found on Defendants' websites, brochures and labels, these products and others promoted and distributed by Defendants are drugs under the Act.

DEFENDANTS DISTRIBUTE PRODUCTS THAT ARE UNAPPROVED NEW DRUGS

17. Under the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval under an investigational new drug application ("IND"). 21 U.S.C. §§ 355(a), (b), (i), and (j).

18. A "new drug" is defined as any drug "the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). For a product to be deemed "generally recognized as safe and effective" ("GRAS/GRAE"), it must have substantial evidence of safety and effectiveness. 21 U.S.C. § 355(d). If it is an over-the-counter ("OTC") drug, the product must comply with a monograph established pursuant to an FDA regulation. 21 C.F.R. § 330.1.

19. The introduction or delivery for introduction into interstate commerce of an unapproved new drug violates the Act. 21 U.S.C. § 331(d).

20. Defendants' drugs are "new drugs" as defined by 21 U.S.C. § 321(p)(1), because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

21. FDA has searched its records for NDA, ANDA, and IND submissions by Defendants. Defendants have no such approvals on file from FDA. Moreover, Defendants' drugs do not conform to any OTC drug monograph. As a result, Defendants' drugs may not be distributed legally in interstate commerce.

CERTAIN OF DEFENDANTS' PRODUCTS ARE MISBRANDED DRUGS

22. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded violates the Act. 21 U.S.C. § 331(a).

23. A drug is misbranded if its label fails to bear "adequate directions for use" as defined by 21 C.F.R. § 201.5(a), and it does not fall within a regulatory exemption from that requirement. 21 U.S.C. § 352(f)(1).

24. "Adequate directions for use" means "directions under which the layman can use a drug safely and for the purpose for which it is intended." 21 C.F.R. § 201.5(a)

25. Defendants' drug products are misbranded under 21 U.S.C. § 352(f)(1) because they lack adequate and well-controlled studies to support the claims made for them. Their labeling therefore necessarily fails to bear adequate directions for use, and, because they are unapproved new drugs, they are not exempt from that requirement. 21 C.F.R. §§ 201.100(c)(2), 201.115.

26. Some of Defendants' drug products are also prescription drugs because of the purposes for which they are intended, including the self-diagnosis and treatment of, among other diseases, Alzheimer's, cancer, fibromyalgia, ADHD, rheumatoid arthritis, and heart disease, and the "collateral measures necessary to [their] use." 21 U.S.C. § 353(b)(1)(A). By definition, prescription drugs cannot contain adequate directions for lay use, see id., causing Defendants' prescription drug products to be misbranded under 21 U.S.C. § 352(f)(1).

DEFENDANTS DISTRIBUTE ADULTERATED DIETARY SUPPLEMENTS

27. The Act defines "dietary supplement" as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of [any of them]." 21 U.S.C. § 321(ff). In addition, a dietary supplement must not be "represented for use as a conventional food or as a sole item of a meal or the diet" and must be "labeled as a dietary supplement." Id. Dietary supplements are deemed to be "food" under the Act, except for purposes of 21 U.S.C. §§ 321(g) and 350f. Id.

28. Defendants' products are labeled as dietary supplements on their principal display panels, as defined in 21 C.F.R. § 101.1. Furthermore, each of Defendants' products contain at least one of the dietary ingredients specified in 21 U.S.C. § 321(ff).

29. The Act requires manufacturers of dietary supplements to operate in compliance with current good manufacturing practice for dietary supplements ("Dietary Supplement cGMP"). 21 U.S.C. § 342(g)(1). Manufacturing according to Dietary Supplement cGMP means that the manufacturing process incorporates a set of controls in the design and production processes to assure a quality finished product. Dietary supplements not manufactured, prepared, packed, or held in conformance with Dietary Supplement cGMP are deemed to be adulterated. 21 U.S.C. § 342(g)(1). The Dietary Supplement cGMP regulations are set forth at 21 C.F.R. Part 111.

30. FDA's January 22, 2013 - February 11, 2013 inspection of Defendants' facility (the "February 2013 inspection") establishes that the dietary supplements that Defendants distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they were prepared, packed, and held in a manner that does not conform to Dietary Supplement cGMP.

Defendants' significant deviations from Dietary Supplement cGMP, include, but are not limited to, the following:

a. Failure to establish an identity specification for each component, as required by 21 C.F.R. § 111.70(b)(1).

b. Failure to conduct at least one appropriate test to verify the identity of a dietary ingredient, as required by 21 C.F.R. § 111.75(h)(1).

c. Failure to prepare a written Master Manufacturing Record ("MMR") for each batch size, as required by 21 C.F.R. § 111.205.

d. Failure of the MMR to include all required information specified by 21 C.F.R. § 111.210.

e. Failure to prepare and follow a written batch production record for each unique formulation of dietary supplement manufactured, as required by 21 C.F.R. § 111.255.

f. Failure of batch production records to include all information required by 21 C.F.R. § 111.260.

DEFENDANTS ENGAGE IN INTERSTATE COMMERCE

31. During the February 2013 inspection, FDA investigators documented records of a shipment of Defendants' products from their Oregon headquarters to California. Defendants Cole and Graves confirmed that, despite their lack of shipping records, the firm regularly ships its products out of state. Such shipments constitute the introduction or delivery for introduction into interstate commerce within the meaning of 21 U.S.C. §§ 331(a) and (d).

32. Prior to distribution, Defendants receive all of their powdered raw materials for their products from a sole source in Massachusetts.

HISTORY

33. Defendants are well aware that their conduct violates the law and that continued violations could lead to regulatory action.

34. FDA sent Defendant James G. Cole, as CEO of Defendant James G. Cole, Inc., a Warning Letter dated February 28, 2003, for making unsubstantiated product claims for Therma Lean, a product containing ephedra.

35. FDA sent Defendant James G. Cole, as CEO of Defendant James G. Cole, Inc., another Warning Letter dated March 11, 2004, for marketing a dietary supplement -- Androstene 100 -- which contained a new dietary ingredient without first providing FDA prior notice.

36. FDA sent Defendant James G. Cole, as CEO of Defendant James G. Cole, Inc., another Warning Letter dated October 12, 2010, about violations for the sale of unapproved new drugs through their www.maxamlabs.com website. The Warning Letter identified twenty-four different products marketed and distributed by Defendants that, based on their labeling claims, were unapproved new drugs under the Act. The Warning Letter instructed Defendants that, under 21 U.S.C. § 331(d), continued distribution of these products was prohibited, and that continued violation of the law could result in legal action. These products included PCA-Rx, a product that Defendants are still marketing for disease treatment.

37. FDA has conducted two recent inspections of the Defendants' facility. At the conclusion of the first inspection (conducted from March 20 - March 23, 2012), FDA issued Defendant Julie Graves a twelve-item List of Inspectional Observations ("FDA Form 483"), detailing Defendants' significant deviations from the Dietary Supplement cGMP requirements. On September 28, 2012, FDA sent Defendants James G. Cole and James G. Cole, Inc., a Warning Letter detailing these ongoing violations and warning Defendants that failure to correct these significant manufacturing problems would result in legal action. Among other identified

violations, the letter highlighted: failure to establish a master manufacturing record; failure to establish component specifications; failure to conduct at least one test or examination to verify the identity of a dietary ingredient; failure to have written procedures for quality control operations; failure to prepare a batch production record; failure to collect and hold reserve samples; and failure to establish and follow written procedures for returned dietary supplements.

38. Despite Defendants' repeated promises for corrective action, the most recent FDA inspection, that concluded on February 11, 2013 and resulted in the issuance of a sixteen-item 483 to Defendant James Cole, revealed Defendants' ongoing failure to follow Dietary Supplement cGMP requirements. See ¶ 30.

39. Defendants' history of promoting products to cure, mitigate, treat, prevent, and/or reduce the risk of diseases including, but not limited to, autism, Alzheimer's, cancer, fibromyalgia, ADHD, rheumatoid arthritis, and heart disease, demonstrates their unwillingness to comply with the Act. Further, Defendants have consistently failed to comply with dietary supplement cGMP requirements. Based on Defendants' recent course of conduct, it is evident that, unless restrained by order of this Court, Defendants will continue to violate the Act, 21 U.S.C. §§ 331(a), (k), and (d).

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done, any of the following acts:

A. Violating 21 U.S.C. § 331(d), by distributing unapproved new drugs in interstate commerce;

B. Violating 21 U.S.C. § 331(a), by distributing misbranded drugs in interstate commerce;

C. Violating 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded;

D. Violating 21 U.S.C. § 331(a), by distributing adulterated dietary supplements in interstate commerce; and,

E. Violating 21 U.S.C. § 331(k), by causing dietary supplements that Defendants hold for sale after shipment interstate commerce to become adulterated;

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from promoting and distributing any drug or dietary supplement unless and until:

A. An approved new drug application or abbreviated new drug application pursuant to 21 U.S.C. § 355(a) or (j) is in effect for the product; or

B. An investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i) is in effect for the product; or

C. Defendants have removed all claims from their product labels, labeling, promotional materials, websites owned or controlled by or related to Defendants, and in any other media that cause that product to be a drug as defined by the Act;

III. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from manufacturing, processing, packing, labeling, holding, or distributing dietary supplements, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, and hold dietary supplements are established, operated, and administered in conformity with Dietary Supplement cGMP and the Act, in a manner that has been found acceptable by FDA;

IV. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug or dietary supplement to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

V. That Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED this 12th day of September, 2013.

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